

**REMARKS**

Claims 27-43 are pending and under examination in the above-identified application. Applicant has review the remarks set forth in the Advisory Action mailed April 19, 2004, and respectfully traverse all grounds for maintaining the rejections of record reasons the that follow.

Regarding formalities, Applicant respectfully requests that all future correspondence regarding this application be directed to Applicant's representative as set forth below. A Revocation of Power of Attorney and Power of Attorney and Change of Mailing Address was filed with the Office on August 27, 2003. Attached as Exhibit A is a copy of the Revocation, New Power of Attorney and Change of Address, including the stamped return postcard showing that the paper was received by the Office.

**Rejections Under 35 U.S.C. § 102**

The Advisory Action maintains the rejection of claims 27-43 under 35 U.S.C. § 102(e) as anticipated by Fan et al., US 2002/0006617 A1, alleging that the priority applications fail to provide written description for rolling circle amplification (RCE). Appearing to maintain an absolute requirement for express written description, the Office asserts that "there is no substitute in the requirement for written description: written description of a method has to be provided, and disclosure of unrelated methods does not provide written description for Applicants' particular method, i.e., RCA." The Office further appears to imply that Applicant concedes that the priority applications lack reference to RCA.

Applicant maintains its previous remarks of record and respectfully requests reconsideration thereof. Applicant pointed out that the priority applications exemplify numerous amplification species sufficient to comply with the written description requirement of the first paragraph of § 112 such that one skilled in the art can recognize the full scope of the invention as claimed. Applicant did not concede that the priority applications lack reference to RCA. Rather, Applicant maintained that the priority applications provide sufficient support and further stated that, although the language in the priority applications allegedly may not be identical to that recited in the claimed invention, there is ample support in the priority applications and in the federal case law to satisfy the written description requirement of § 112, first paragraph.

In its response filed March 19, 2004, Applicant set forth exemplary descriptions within the priority applications which provide adequate written description sufficient to show Applicant was in possession of the claimed invention as of the priority date. Application serial no. 60/135,053, (the '053 application), for example, describes the use of nucleic acid probes and hybridization for detection of a target sequence, including for example, ligation chain reaction (LCR or OLA), Invader<sup>TM</sup> technology, single base extension technology, competitive probe binding and sequencing by synthesis. Exemplary primer configurations are further described therein, including configurations for OLA, LCR, CPT (cycling probe technology) and Invader<sup>TM</sup>. competitive probe analysis, pyrosequencing, PCR, SDA (strand displacement amplification), NASBA (nucleic acid sequence based amplification), and "branched DNA" signal amplification

The '053 application further describes various amplification reaction formats and the use of amplification probes. Exemplary amplification methods include the polymerase chain reaction (PCR), strand displacement amplification (SDA) and nucleic acid sequence based amplification (NASBA), ligase chain reaction (LCR), cycling probe technology (CPT), Invader<sup>TM</sup> technology, Q-Beta replicase (Q $\beta$ R) technology, and the use of amplification probes such as branched DNA that result in multiple labeled probes as well as other amplification methods.

Therefore, the application describes numerous amplification methods well known in the art that can be used for detecting a target molecule by, for example, amplifying the target or by, for example, amplifying the target probe. Further, the '053 application exemplifies ten additional PCR methodologies that can be employed in the amplification of a target or probe sequence. Except for the general method of PCR, none of the additional ten PCR variations are redundant with the other amplification methodologies described above and taught in the '053 application. Therefore, the application exemplifies at least 18 different amplification methods well known in the art that can be used for amplicon formation in the methods of the invention.

Additionally, Applicant specifically pointed to strand displacement amplification (SDA) described in the '053 application and submitted evidence that amplification of a circular nucleic acid proceeds through a strand displacement mechanism (see, for example, Exhibits A and B attached to Applicant's response filed March 19, 2004). The submitted exhibits corroborate that

the descriptions in the '053 application exemplify the use of a circular template as a further amplification method described in the application. Accordingly, the descriptions in the priority application provide sufficient written description for the claimed rolling circle amplification (RCA)

These descriptions, including amplification using strand displacement as set forth above and in Applicant's previous response, are sufficient to show that Applicant intended all forms of amplification methods well known in the art to be used in the methods of the invention. Rolling circle amplification is one such method well known in the art. The numerous amplification methods and species thereof described in the priority application would provide one skilled in the art with the understanding that other well known amplification methods were intended to be included within the scope of the invention. Accordingly, these exemplary amplification descriptions show that one skilled in the art would understand that Applicant was in possession of rolling circle amplification at the time the '053 application was filed.

Applicant further directed the Office to the federal authority which clearly indicates that compliance with written description does not require that the application describe the claimed invention in *ipsis verbis*. *Application of Edwards*, 568 F.2d 1349, 1351-52 (C.C.P.A. 1978); *accord Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1376, (Fed.Cir. 2002) ("the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter"); *New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1296 (Fed. Cir. 2002) ("[i]dentity of description is not necessary"). More recently, the Federal Circuit reaffirmed that compliance with the written description requirement can be satisfied by principles of inherency when the court reasoned:

[I]t is true that this court and its predecessor have repeatedly held that claimed subject matter "need not be described *in haec verba*" in the specification to satisfy the written description requirement.

*University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 922-23 (Fed. Cir. 2004) *citing In re Smith*, 481 F.2d 910, 914 (CCPA 1973). As described above and in Applicant's previous response, the priority applications adequately describe a nucleic acid amplification as claimed sufficient to show possession of the claimed invention.

Further, the Office cites Fan et al., US 2002/0006617 A1 (Fan et al.) alleging that this publication anticipates the claimed invention. Fan et al. corresponds to a utility application filed February 7, 2001, and claims the benefit of priority to provisional applications 60/234,732 (the '732 application) filed September 22, 2000, and 60/180,810 (the '810 application) filed February 7, 2000.

The subject application is a continuation application claiming priority to U.S. application 09/517,945, filed March 3, 2000. Therefore, the effective filing date for the above-identified application is March 3, 2000. Because Fan et al. was filed after the effective date of the above-identified application, it cannot form a basis for an rejection under § 102(e) except to the extent the relevant subject matter was described in a priority application filed prior to Applicant's effective date of March 3, 2000. The '810 application is the only application satisfying this criteria and therefore must describe rolling circle amplification (RCA) in sufficient detail to enable Fan et al. to form a proper basis for rejection.

However, the Office has not established that the priority '810 application describes rolling circle amplification or describes any other element of the claimed invention. If the Office continues to assert Fan et al. as a basis for rejection, Applicant respectfully requests that the Office particularly point out support for each element of the claimed invention in the '810 application.

In addition, if the current rejection is maintained on the basis of lack written description in the priority applications, Applicant additionally requests that the Office satisfy its burden to establish sufficiency of the written description rejection and provide reasons why a description not in *ipsis verbis* is insufficient. *Application of Edwards*, 568 F.2d at 1354. Here, the Office appears to conclude that the claimed method lacks support in, for example, the '053 application, since the term "RCA" is allegedly not described. Such broad conclusions are insufficient to establish the Office's burden in failing to accord priority to the claimed invention.

In light of the above remarks, Applicant contends that the claimed invention is adequately described to be accorded benefit of their filing dates and respectfully requests that the rejection over Fan et al. be withdrawn.

### **Rejections Under 35 U.S.C. § 103**

The rejection of claims 27-41 and 43 under 35 U.S.C. § 103(a) is maintained as allegedly obvious over Taylor, US 2002/0168645, in view of Walt et al., U.S. Patent No. 6,023,540. The Office asserts that Applicant's arguments, that the arrays of Taylor do not provide a connection because they are used for a different purpose, are unpersuasive allegedly because Applicant's claimed arrays also are not used for the purpose of amplification. Rather, the Office asserts that Applicant's arrays are used for the purpose of hybridization of amplified products.

If the Office maintains this ground of rejection, Applicant respectfully requests a further explanation of the above reasoning. It appears that the various purposes referenced in the Advisory Action are improperly relied upon. Applicant respectfully points out that the purpose of the claimed invention is immaterial except in so far that it can be compared to the alleged purpose for combining cited art that is sufficiently similar. Here, the purpose of the cited art differs from the purpose of the claimed invention. Because the purpose differs, the cited art fails to suggest or provide motivation one skilled in the art to combine Taylor with Walt et al. to obtain the invention as claimed. *Brown & Williamson Tobacco v. Philip Morris*, 229 F.3d 1120, 1124 (Fed. Cir. 2000). Accordingly, the cited references do not render the claimed invention obvious and withdrawal of this ground of rejection is respectfully requested.

### **CONCLUSION**

In light of the Remarks herein, Applicant submits that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, she is invited to call the undersigned attorney.

Serial No.: 10/021,906

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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